

JULIUS TABIN JOHN F. FLANNERY ROBERT B. JONES JAMES J. SCHUMANN JAMES J. HAMILL TIMOTHY E. LEVSTIK JOSEPH E. SHIPLEY KENNETH H. SAMPLES PHILIP T. PETTI JOSEPH T. NABOR STEVEN C. SCHROER RICHARD A. KABA* KARL R. FINK MARK W. HETZLER TIMOTHY P. MALONEY JAMES P. KRUEGER STEPHEN S. FAVAKEH RICHARD E. WAWRZYNIAK STEVEN G. PARMELEE THOMAS F. LEBENS BRUCE R. MANSFIELD KENDREW H. COLTON G. PAUL EDGELL MICHAEL A. SANZO* SCOTT A. MENGHINI NORMAN N. KUNITZ*

RUDY KRATZ

RAMON R. HOCH*

FITCH, EVEN, TABIN & FLANNERY

ATTORNEYS AND COUNSELLORS AT LAW

Established in 1859

SUITE 401L - 1801 K STREET, NW WASHINGTON, D.C. 20006-1201 TELEPHONE (202) 419-7000 FACSIMILE (202) 419-7007

ILLINOIS OFFICE

SUITE 1600 - 120 SOUTH LA SALLE STREET, CHICAGO, ILLINOIS 60603-3406
TELEPHONE (312) 577-7000

CALIFORNIA OFFICE

SUITE 250-9276 SCRANTON ROAD, SAN DIEGO, CA 92121-7708 TELEPHONE (858) 552-1311

COLORADO OFFICE SUITE 213 - 1942 BROADWAY, BOULDER, COLORADO 80302 TELEPHONE (303) 402-6966

August 5, 2004

EDWARD E. CLAIR
JON A. BIRMINGHAM
JOHN E. LYHUS
STEVEN M. FREELAND
DONNA E. BECKER
MICHAEL G. VRANICAR
BRIAN S. CLISE
MARTIN R. BADER
DEREK L. PRESTIN
MARK A. BORSOS
DAVID R. JAGLOWSKI
TIMOTHY R. BAUMANN
JEFFREY A. CHELSTROM
NICHOLAS T. PETERS
KENNETH A. PLOCHINSKI
MEGAN J. REDMOND

PATENT AGENTS

ERIC J. WHITESELL LILIA I. SAFONOV

OF COUNSEL

GEORGE W. SPELLMIRE, JR. LISA M. SOMMER GEORGE H. SPENCER, P.C.*

TECHNICAL ADVISOR

JOHN M. BRONK, PH.D.

*ADMITTED TO D.C. BAR; D.C. PRACTICE OF ALL OTHERS LIMITED TO FEDERAL COURTS

Commissioner of Patents
U.S. Patent and Trademark Office
220 20th Street South
Customer Window, **MS Reissue**Crystal Plaza Two, Lobby, Room 1B03
Arlington, VA 22202

Re:

Second Supplemental Information Disclosure Statement

Appl. No.:

10/811,793

Filed:

March 29, 2004

Title:

Water 29, 2004

-

Treatment of Migraine Headache

Inventor(s):

Plachetka, et al.

Atty. Dkt.:

7569/80993

Dear Sir:

The following documents are being forwarded for appropriate action by the U.S. Patent and Trademark Office:

- 1. Second Supplemental Information Disclosure Statement;
- 2. PTO Form-1449, List of References Cited by Applicant;
- 3. Reference AL1; and
- 4 Return postcard.

Applicants do not believe that any fee is due for the filing of this Information Disclosure Statement. However, the Director is hereby authorized to charge any fee deficiency with respect to this filing and any other fee required in connection with the present case, or credit any overpayment, to our Deposit Account No. 06-1135 under Order No. 7569/80993.

Commissioner for Patents August 5, 2004 Page 2

It is respectfully requested that the enclosed postcard be stamped with the date the enclosed documents are received by the PTO and that it be returned as soon as possible.

Very truly yours,

FITCH, EVEN, TABIN & FLANNERY

Michael A. Sang

Michael A. Sanzo Reg. No. 36,912

Attorney for Applicants

MAS:ct Enclosures



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re reissue patent application of:

Plachetka, et al.

Appl. No.: 10/811,793

Filed: March 29, 2004

For: Treatment of Migraine Headache

Art Unit: to be assigned

Examiner: to be assigned

Atty. Dkt.: 7569/80993

Second Supplemental Information Disclosure Statement

Commissioner of Patents
U.S. Patent and Trademark Office
220 20th Street South
Customer Window, **MS Reissue**Crystal Plaza Two, Lobby, Room 1B03
Arlington, VA 22202

Sir:

Submitted herewith is a listing of documents known to Applicants and/or their attorney in compliance with the requirements of 37 C.F.R. § 1.56. Copies of the listed documents are also enclosed.

The document listed on the enclosed List of References is a Press Release indicating that the FDA did not approve Pozen's MT 100 product, which is a preparation containing naproxen sodium and metoclopramide. Applicants are continuing to work with the FDA to resolve the issues raised in their non-approval letter.

Applicants do not waive any rights to appropriate action to establish patentability over any of the listed documents should they be applied as references against the claims of the present application. This statement should not be construed as a representation that more material information does not exist or that an exhaustive search of the relevant art has been made.

Consideration of the cited documents and making the same of record in the prosecution of the above-captioned application are respectfully requested.

Applicants do not believe that any fee is due for the filing of this Information Disclosure Statement. However, the Commissioner is hereby authorized to charge any fee deficiency to our Deposit Account No. 06-1135 under Order No. 7569/80993.

Respectfully submitted,

FITCH, EVEN, TABIN & FLANNERY

Michael A. Sanzo

Reg. No. 36,912 Attorney for Applicants

Date 🖊

1801 K Street, N.W., Suite 401L

Washington, DC 20006-1201

Phone: (202) 419-7013

					ty. Docket No.: 7569/80993	Appl No.: 10/811,793				
CISTOF REFERENCES CITED BY APPLICANT (Jse several sheets if necessary)					Applicant(s) Plachetka, et al.					
AUG 0 5 2004 E					ling Date: March 29, 2004	Group: to be assigned				
U.S. PATENT DOCUMENTS										
Examiner Document				Filing Date						
Initial		Number	Date	Naı	ame	Class				
	AA 1	-								
	AB 1									
	AC 1									
	AD 1									
	AE 1									
	AF 1	.								
	AG 1									
FOREIGN PATENT DOCUMENTS										
								Translation		
		Document Number	Date	Coı	Country	Class	Subclass	Yes	No	
	AH 1		7							
	AI I									
	AJ 1									
	AK 1				-					
	OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.) AL 1 Copy of Press Release indicating Non-Approval of MT 100 Product of Pozen.									
	AM 1				F. 60 - 74 - 9					
	AN 1		****							
•	AO 1									
	AP 1	·								
	AQ 1						·			
	AR 1									
	AS 1									
Examiner				D	Date Considered					